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PROTOCO$_2$L™ Insufflator With Performance Improvements 510(k) Summary

APR 1 6 2003

Submitter's Information:	E-Z-EM, Inc. 717 Main Street Westbury, NY 11590
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Contact:	Judy Hauser, Sr. Manager Regulatory Affairs
Date Prepared:	March 13, 2003
Trade Name:	PROTOCO$_2$L™ Colon Insufflator with Performance Improvements
Common Name:	Insufflator, Colonic
Classification Name:	Endoscope and accessories 21 CFR 876.1500 78 FCX
Predicate Device:	PROTOCO$_2$L™ Colon Insufflator K013219

Indications for Use:

The E-Z-EM PROTOCO$_2$L COLON Insufflator administers and regulates carbon dioxide (CO_2) as a distention media to the colon during CT Colonography (CTC or Virtual Colonoscopy) and conventional Colonoscopy.

Device Description:

The EZEM PROTOCO$_2$L with performance improvements, as with the predicate device is an insufflation system that is used in conjunction with a consumable and is intended to displace and regulate carbon dioxide (CO_2) as a distention media to a patient's colon for purposes of CT Colonography and conventional colonoscopy. As with the predicate, the PROTOCO$_2$L system with performance improvements consists of 3 components. These are the insufflator, consumable and accessory cart.

The performance improvements presented here do not affect or change the current indications and contraindications of the PROTOCO$_2$L device. A summary of the performance specification improvements as compared to the predicate performance specifications are stated as follows:

Proposed Performance Specification	Predicate Performance Specification
Start-Up Ramp At the onset of the procedure, flow of CO_2 to the patient to be ramped to the patient in accordance with the following increments: 1.0 Liters/Minute for 0 to 0.5 Liter of Delivered Volume 2.0 Liters/Minute for greater than 0.5 to 1.0 Liter Delivered Volume 3.0 Liters/Minute for Delivered Volumes Greater than 1.0 Liter	**Start-Up Ramp** At the onset of the procedure, flow of CO_2 to the patient initiates itself to the specified flow rate of: 3 Liters/Minute
Pressure Relief Electronic Pressure Relief 50 mm Hg for 5 seconds (absolute) Independent Redundant Mechanical Relief 75 mm Hg	**Pressure Relief** Electronic Pressure Relief 6 mm Hg-second (relative) Independent Redundant Mechanical Relief 50 mm Hg
Volume Delivery Upon Pressing the RUN/STOP Button at the start of the procedure, the unit will remain in run mode until 4 Liters of CO_2 have been delivered. Once 4 Liters has been delivered, the unit automatically returns to stop mode. Thereafter pressing the RUN/STOP button a 2nd time will resume the delivery of CO_2 for an additional 2 Liters of CO_2. Once an additional 2 Liters has been delivered, the unit automatically returns to stop mode.	**Volume Delivery** Upon pressing the RUN/STOP button at the start of the procedure, the unit will remain in run mode indefinitely until the user presses this button a second time to stop CO_2 delivery. Thereafter pressing the RUN/STOP button a 3rd time will resume the delivery of CO_2 indefinitely until the user presses the button to stop CO_2delivery.

Subsequent presses of the RUN/STOP button will deliver additional 2 Liter boluses of CO2 as required by the user. The user can always depress the RUN/STOP button during any of these volume increments to STOP delivery of CO2.	

As with the predicate PROTOCO$_2$L design, the PROTOCO$_2$L with performance improvements unit is still based on the currently marketed Northgate 3315/6600 Insufflator product that is designed and manufactured by Northgate Technologies (OEM manufacturer), Elgin, Illinois (Model No. 6400). Other than the performance improvements outlined here, there are no changes to the insufflator cart and tubing set as prescribed by the original 510(k) for this device.

Comparative Information Regarding Substantial Equivalence:

The EZEM PROTOCO$_2$L Colon Insufflator with performance improvements and the original PROTOCO$_2$L Colon Insufflator are indicated for distention of the Colon during CT Colonography (CTC or Virtual Colonoscopy) and conventional Colonoscopy.

The proposed and predicate PROTOCO$_2$L Colon Insufflator rely on proven and widely accepted gas metering technology to precisely regulate the flow, volume and pressure of CO2 on a continuous basis. With this technology the user has direct digital feedback on the actual colon pressure and distention volume for the duration of the procedure.

In summary both the proposed PROTOCO$_2$L Colon Insufflator with performance improvements and the predicate PROTOCO$_2$L Colon Insufflator:

- Use CO_2 as a colon distention media for radiographic exams
- Use electronically controlled metering of CO_2
- Have the same operating principle and fundamental scientific technology
- Allow for the adjustment of distention pressure
- Have the same maximum delivery pressure
- Have the same volume delivered display
- Have the same digital display of pressure and distention volume
- Use the same hydrophobic filter technology to prevent contamination of the device
- Are made from the same materials
- Specify use of an enema tip (rectal catheter) for colon access

Where their significant differences are:

- The Flow Rate for the initial volume of CO_2 is gradually increased to 3 Liters/Minute versus initially delivering at 3 Liters/Minute.

- During delivery, pre-defined volume increments at 4 liters of CO_2 and thereafter 2 liter volumes are administered versus continuous volume delivery until the operator intervenes.
- Electro-pneumatic pressure relief valve is at 50 mmHg for 5 seconds versus a relative 6 mm Hg – second pressure relief relative to set pressure.
- Independent redundant mechanical pressure relief at 75 mm Hg.

A comparison between the EZEM PROTOCO$_2$L with software modifications and the predicate PROTOCO$_2$L device is presented in the following tables.

Comparative Summary Tables

	Proposed Device	Predicate Device
Insufflator Unit, General	**E-Z-EM PROTOCO$_2$L WITH PERFORMANCE IMPROVEMENTS**	**E-Z-EM PROTOCO$_2$L**
Indication for Use	Administer and regulate CO_2 as a distention media for the colon during CT Colonography (CTC or Virtual Colonoscopy) and conventional colonoscopy.	Same as proposed
Design	Electro-Mechanical Pneumatic System to regulate both Flow and Pressure of CO_2	Same as proposed
Anatomical Sites	Rectal administration of CO_2 via enema tip or catheter lumen	Same as proposed
Radiation	No ionizing radiation emitted	Same as proposed
Thermal	No thermal energy introduced into patient	Same as proposed

	Proposed Device	Predicate Device
Insufflator Unit, General	**E-Z-EM PROTOCO$_2$L WITH PERFORMANCE IMPROVEMENTS**	**E-Z-EM PROTOCO$_2$L**
Insufflation Unit	Located Adjacent to CT Gantry	Same as Proposed
Power Supply	Switching Power Supply in Dedicated Enclosure	Same as Proposed
Flow Rate	1 to 3 Liters/Minute based on the volume delivered; Flow is ramped up during first Liter: Delivery volume from 0 to 0.5 Liter @ 1 Liter/Minute maximum Delivery volume greater than 0.5 to 1 Liter @ 2 Liters/Minute maximum Delivery volume greater than 1 Liter @ 3 Liters/Minute maximum Accuracy: Not to exceed + 20% @ 3 Liters/ minute	1 to 3 Liters/Minute, Fixed Accuracy: Not to exceed + 20% @ 3 Liters/ minute
Delivery Pressure	0 to 25 mm Hg in increments of 1 mm Hg Accuracy: +/- 10%	Same as proposed

Insufflator Unit, General	Proposed Device E-Z-EM PROTOCO$_2$L WITH PERFORMANCE IMPROVEMENTS	Predicate Device E-Z-EM PROTOCO$_2$L
Delivery Volume	1 to 999 Liters in 0.1 Liter increments Accuracy: +/- 20 %	Same as proposed
Pressure Limiting	Yes	Yes
Over-Pressure Relief	Yes Electrical Relief Valve opens when colon pressure goes above 50 mmHg for sustained 5 seconds Independent redundant Mechanical Relief Valve opens when colon pressure is at 75 mmHg	Yes Electrical Relief Valve opens when colon pressure exceeds set pressure by 5 mmHg for 2 seconds Independent redundant Mechanical Relief Valve opens when colon pressure is at 50 mmHg

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	Proposed Device	Predicate Device
Insufflator Unit, 'splays and Controls	**E-Z-EM PROTOCO$_2$L WITH PERFORMANCE IMPROVEMENTS**	**E-Z-EM PROTOCO$_2$L**
Display	Insufflation Pressure: 2-Seven Segment LEDs Volume: 3-Seven Segment LEDs Supply Volume: Graduated LED Array	Same as Proposed
Pressure	Rotary Adjustment Knob	Same as Proposed
Flow Rate	Fixed, No Adjustment	Same as Proposed
Power	Single Acting Button	Same as Proposed
Stop/Run	Single Acting Button	Same as Proposed
Volume Reset	Single Acting Button	Same as Proposed
Over Pressure Alarm Reset	Single Acting Button	Same as Proposed
Consumable Connection	Medical, CPC locking Connection	Same as Proposed

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	Proposed Device	Predicate Device
Insufflator Unit, Environmental Requirements	**E-Z-EM PROTOCO$_2$L WITH PERFORMANCE IMPROVEMENTS**	**E-Z-EM PROTOCO$_2$L**
Operating Temperature Operating Humidity, Operating Altitude & Storage Temperature	Meets Requirements set forth in IEC/EN60601-1, Medical Electrical Equipment Part 1: General Requirements for Safety	Same as proposed
Electromagnetic Compatibility (EMC)	Meets Requirements set forth in IEC/EN 60601-1-2, Medical Electrical Equipment Part 1: Collateral Standard, Electromagnetic Compatibility CISPR 11 IEC 801-2 IEC 801-3 IEC 801-4 IEC 801-5	Same as proposed
UL/CSA	Medical Device Listing to UL 2601-1 / CSA C22.2 No. 601.1, Electrical Class I, Type B Isolation rating	Same as proposed

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	Proposed Device	Predicate Device
Insufflator Unit, Environmental Requirements	**E-Z-EM PROTOCO$_2$L WITH PERFORMANCE IMPROVEMENTS**	**E-Z-EM PROTOCO$_2$L**
Energy Requirements	100/240 VAC 50/60 Hz Auto Seeking	Same as proposed
Shock and Vibration	International Safe Transit Authority (ISTA), Project 3C	Same as proposed

Insufflator Consumable	Proposed Device E-Z-EM PROTOCO$_2$L WITH PERFORMANCE IMPROVEMENTS	Predicate Device E-Z-EM PROTOCO$_2$L
Consumable Tubing Set	E-Z-EM Designed and Manufactured non-sterile tubing set using existing enema tip for rectal access.	Same as proposed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 16 2003

Ms. Judy Hauser
Sr. Manager Regulatory Affairs
E-Z-EM, Inc.
717 Main Street
WESTBURY NY 11590

Re: K030854
Trade/Device Name: E-Z-EM PROTOCO$_2$L Colon Insufflator
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FCX
Dated: March 17, 2003
Received: March 18, 2003

Dear Ms. Hauser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Application: Special 510(k)

Device Name: E-Z-EM PROTOCO$_2$L COLON INSUFFLATOR

Indications for Use:

The E-Z-EM PROTOCO$_2$L COLON Insufflator administers and regulates carbon dioxide (CO_2) as a distention media to the colon during CT Colonography (CTC or Virtual Colonoscopy) and conventional Colonoscopy.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030854